Alfa Scientific Designs, Inc.
FDA Registered • ISO 9001/EN 46001 Certified
In-Vitro Diagnostic (IVD) Devices Manufacturer • Contract R&D • OEM

I.S. EN ISO 9001
I.S. EN 46001

MAY - 7 2007

K063545

510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: (858) 513-3888 x 325 Fax: (858) 513-8388
	Contact Person:	Daiting Rong, Ph.D. E-mail:drong@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW®* Amphetamine (300) Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT®* Amphetamine (300) Urine Test (Cassette, Dip-Strip) Amphetamine (300) Urine Test (Cassette, Dip-Strip)
	Common Name:	Immunoassay, AMP Urine Test
	Classification:	Amphetamine Test System
	Product Code:	DKZ
Date of Summary Preparation		Nov. 16, 2006
Predicate Devices		*INSTANT-VIEW®* Amphetamine Urine Test (510K Number: K994395) By Alfa Scientific Designs, Inc.
Device Description		This assay is a one-step lateral flow chromatographic immunoassay. The test strip consists of 1) a burgundy-colored conjugate pad containing mouse anti-amphetamine antibodies and rabbit IgG coupled to colloidal gold; and 2) a nitrocellulose membrane containing a Test (T) line and a Control (C) line. The T line is coated with amphetamine-BSA, and the C line is coated with goat anti-rabbit IgG antibody.

Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of amphetamine in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The proposed test is for professional and point of care use only.
Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Sensitivity and Specificity	The sensitivity of the proposed device is 93.5% and the specificity is 98%
Accuracy	Ninety-eight clinical confirmed specimens for AMP were studied, separately. The overall agreement of the AMP (300) device to the GC/MS data is 96.9%.
Reproducibility	Studies were carried out at two Physician's Office Laboratories (POL) and one medical reference laboratory outside Alfa. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The agreement of the three sites is 97.5%.
Stability	To assess the shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results of the accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, did not affect the test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette format is a dip-strip device assembled in a plastic housing. Studies demonstrated that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

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	Address:	13200 Gregg Street Poway, CA 92064 Telephone: (858) 513-3888 x 325 Fax: (858) 513-8388
	Contact Person:	Daiting Rong, Ph.D. E-mail:drong@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW*® Cocaine (150) Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT*® Cocaine (150) Urine Test (Cassette, Dip-Strip) Cocaine (150) Urine Test (Cassette, Dip-Strip)
	Common Name:	Immunoassay, Cocaine Urine Test
	Classification:	Cocaine Test System
	Product Code:	DIO
Date of Summary Preparation		Nov. 16, 2006
Predicate Devices		*INSTANT-VIEW*® Cocaine Urine Test (510K Number: K994403) By Alfa Scientific Designs, Inc.
Device Description		This assay is a one-step lateral flow chromatographic immunoassay. The test strip consists of 1) a burgundy-colored conjugate pad containing mouse anti- benzoylecgonine (cocaine) antibodies and rabbit IgG coupled to colloidal gold; and 2) a nitrocellulose membrane containing a Test (T) line and a Control (C) line. The T line is coated with benzoylecnine-BTG, and the C line is coated with goat anti-rabbit IgG antibody.

Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of cocaine (benzoylecgonine) in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The proposed test is for professional and point of care use only.
Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Sensitivity and Specificity	The sensitivity of the proposed device are 96.4% and the specificity is 98.1%
Accuracy	One hundred and eight clinical confirmed specimens for COC were studied, separately. The overall agreement of the COC (150) device to the GC/MS data is 97.2%.
Reproducibility	Studies were carried out at two Physician's Office Laboratories (POL) and one medical reference laboratory outside Alfa. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The agreement of the three sites is 97.9%.
Stability	To assess the shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results of the accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, did not affect the test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette format is a dip-strip device assembled in a plastic housing. Studies demonstrated that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

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Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: (858) 513-3888 x 325 Fax: (858) 513-8388
	Contact Person:	Daiting Rong, Ph.D. E-mail:drong@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW*® Methamphetamine (300) Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT*® Methamphetamine (300) Urine Test (Cassette, Dip-Strip) Methamphetamine (300) Urine Test (Cassette, Dip-Strip)
	Common Name:	Immunoassay, Methamphetamine Urine Test
	Classification:	Methamphetamine Test System
	Product Code:	DJC
Date of Summary Preparation		Nov. 16, 2006
Predicate Devices		*INSTANT-VIEW*® *Metha*mphetamine Urine Test (510K Number: K003845) By Alfa Scientific Designs, Inc.
Device Description		This assay is a one-step lateral flow chromatographic immunoassay. The test strip consists of 1) a burgundy-colored conjugate pad containing mouse anti-methamphetamine antibodies and rabbit IgG coupled to colloidal gold; and 2) a nitrocellulose membrane containing a Test (T) line and a Control (C) line. The T line is coated with methamphetamine-BSA, and the C line is coated with goat anti-rabbit IgG antibody.

Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of methamphetamine in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The proposed test is for professional and point of care use only.
Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Sensitivity and Specificity	The sensitivity of the proposed device is 96.8% and the specificity is 98%
Accuracy	One hundred twenty-seven clinical confirmed specimens for MET were studied, separately. The overall agreement of the MET (300) device to the GC/MS data is 96.1 %.
Reproducibility	Studies were carried out at two Physician's Office Laboratories (POL) and one medical reference laboratory outside Alfa. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The agreement of the three sites is 97.1%.
Stability	To assess the shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results of the accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, did not affect the test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette format is a dip-strip device assembled in a plastic housing. Studies demonstrated that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

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Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: (858) 513-3888 x 325 Fax: (858) 513-8388
	Contact Person:	Daiting Rong, Ph.D. E-mail:drong@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW®* Oxycodone (100) Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT®* Oxycodone (100) Urine Test (Cassette, Dip-Strip) Oxycodone (100) Urine Test (Cassette, Dip-Strip)
	Common Name:	Immunoassay, Oxycodone Urine Test
	Classification:	Opiate Test System
	Product Code:	DJG
Date of Summary Preparation		Nov. 16, 2006
Predicate Devices		OXYCODONE One Step Oxycodone Test Strip (510K Number: K033047) By Acon Laboratories, Inc.
Device Description		This assay is a one-step lateral flow chromatographic immunoassay. The test strip consists of 1) a burgundy-colored conjugate pad containing mouse anti-oxycodone antibodies and rabbit IgG coupled to colloidal gold; and 2) a nitrocellulose membrane containing a Test (T) line and a Control (C) line. The T line is coated with oxycodone-BSA, and the C line is coated with goat anti-rabbit IgG antibody.

Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of oxycodone in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The proposed test is for professional and point of care use only.
Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Sensitivity and Specificity	Both the sensitivity and the specificity of the proposed device are 97.6%
Accuracy	Seventy-five clinical confirmed specimens for OXY were studied, separately. The overall agreement of the OXY (100) device to the GC/MS data is 97.6 %.
Reproducibility	Studies were carried out at two Physician's Office Laboratories (POL) and one medical reference laboratory outside Alfa. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The agreement of the three sites is 96.7%.
Stability	To assess the shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results of the accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, did not affect the test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette format is a dip-strip device assembled in a plastic housing. Studies demonstrated that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

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	Contact Person:	Daiting Rong, Ph.D. E-mail:drong@alfascientific.com
Device Name	**Trade Name:**	*INSTANT-VIEW®* Oxycodone (300) Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT®* Oxycodone (300) Urine Test (Cassette, Dip-Strip) Oxycodone (300) Urine Test (Cassette, Dip-Strip)
	Common Name:	Immunoassay, Oxycodone Urine Test
	Classification:	Opiate Test System
	Product Code:	DJG
Date of Summary Preparation		Nov. 16, 2006
Predicate Devices		OXYCODONE One Step Oxycodone Test Strip (510K Number: K033047) By Acon Laboratories, Inc.
Device Description		This assay is a one-step lateral flow chromatographic immunoassay. The test strip consists of 1) a burgundy-colored conjugate pad containing mouse anti-oxycodone antibodies and rabbit IgG coupled to colloidal gold; and 2) a nitrocellulose membrane containing a Test (T) line and a Control (C) line. The T line is coated with oxycodone-BSA, and the C line is coated with goat anti-rabbit IgG antibody.

Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of oxycodone in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The proposed test is for professional and point of care use only.
Comparison with the Predicate	Similarity • Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly Difference • The cutoff value is 100 ng/ml for the predicate device and 300 ng/ml for the proposed device
Sensitivity and Specificity	The sensitivity of the proposed device is 95.2% and the specificity is 100%
Accuracy	One hundred fifteen clinical confirmed specimens for OXY were studied, separately. The overall agreement of the OXY (300) device to the GC/MS data is 98.3 %.
Reproducibility	Studies were carried out at two Physician's Office Laboratories (POL) and one medical reference laboratory outside Alfa. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. The agreement of the three sites is 97.5%.
Stability	To assess the shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results of the accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, did not affect the test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette format is a dip-strip device assembled in a plastic housing. Studies demonstrated that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

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Address: 13200 Gregg Street
Poway, CA 92064
Telephone: (858) 513-3888 x 325
Fax: (858) 513-8388

Contact Person: Daiting Rong, Ph.D.
E-mail:drong@alfascientific.com

Device Name

Trade Name:

INSTANT-VIEW® Multi-Drug of Abuse Urine Test (Panel, Cup)

INSTANT-VERDICT® Multi-Drug of Abuse Urine Test (Panel, Cup)

Multi-Drug of Abuse Urine Test (Panel, Cup)

Common Name:

Immunoassay, Drug of Abuse Screen Urine Test

Classification:

Amphetamine Test System, Barbiturate Test System, Benzodiazepine Test System, Cocaine and Cocaine Metabolite Test System, Methamphetamine Test System, Opiate Test System, Propoxyphene Test System, Cannabinoid Test System, Tricyclic Antidepressant Drugs Test System, Phencyclidine Test System

Product Code:

DKZ, DIS, JXM, DIO, DJC, DJG, JXN, LDJ, LEG, LCM

Date of Summary Preparation

October 31, 2006

Predicate Devices	*INSTANT-VIEW*® Multi-Drugs Urine Test (510K Number: K022564) *INSTANT-VIEW*® Propoxyphene Test (510K Number: K022915) *INSTANT-VIEW*® TCA Urine Test (510K Number: K022693) *INSTANT-VIEW*® MDMA Urine Test (510K Number: K022501) *INSTANT-VIEW*® BUP/NBUP Urine Test (510K Number: K060527) *INSTANT-VIEW*® Amphetamine Urine Test (510K Number: K994395) *INSTANT-VIEW*® Methamphetamine Urine Test (510K Number: K003845) *INSTANT-VIEW*® Cocaine Urine Test (510K Number: K994403) All by Alfa Scientific Designs, Inc.
	Oxycodone Test (510K Number: K033047) by Acon Laboratories, Inc.
Device Description	A one-step lateral flow chromatographic immunoassay. The device consists of any combination between one (1) to twelve (12) individual test strip(s) for the drug(s) being tested. Each test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a burgundy-colored band during test regardless of the presence of the drug.
Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of one or more drugs or drug metabolites in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. The proposed test is for health care professional including point of care use.
Similarity to the Predicate Devices	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly

Performance Characteristics	The proposed multi-drug of abuse device uses exactly the same technology and formulations for the detection of the drugs as individual test devices. The performance characteristics, such as accuracy, reproducibility, sensitivity and specificity of the multi-drug of abuse test are exactly the same as the individual tests, which have been 510(K) cleared previously or are filed in separated sections of this submission.
Stability	The shelf life stability of the test devices was estimated based on the accelerated degradation studies of individual test devices, three lots for each test, each format. Two years (24 months) shelf life of the proposed tests was predicted.
Formats of the Device	The proposed multi-drug of abuse device has two formats, cassette and urine cup. Both formats contain between one to twelve test strips, each for a drug.
Conclusion	The proposed test is substantially equivalent to the predicate device.

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Contact Person: Daiting Rong, Ph.D.
E-mail:drong@alfascientific.com

Device Name

Trade Name:

INSTANT-VIEW® Multi-Drug of Abuse Urine Test (Panel, Cup)

INSTANT-VERDICT® Multi-Drug of Abuse Urine Test (Panel, Cup)

Multi-Drug of Abuse Urine Test (Panel, Cup)

Common Name:

Immunoassay, Drug of Abuse Screen Urine Test

Classification:

Amphetamine Test System, Barbiturate Test System, Benzodiazepine Test System, Cocaine and Cocaine Metabolite Test System, Methamphetamine Test System, Opiate Test System, Cannabinoid Test System, Tricyclic Antidepressant Drugs Test System, Phencyclidine Test System

Product Code:

DKZ, DIS, JXM (NFV), DIO, DJC, DJG (NCI), JXN, LDJ, LEG, LCM

Date of Summary Preparation

October 31, 2006

Predicate Devices

INSTANT-VIEW® Multi-Drugs Urine Test (510K Number: K022564)

INSTANT-VIEW® TCA Urine Test (510K Number: K022693)

INSTANT-VIEW® MDMA Urine Test (510K Number: K022501)

INSTANT-VIEW® Amphetamine Urine Test (510K Number: K994395)

INSTANT-VIEW® Methamphetamine Urine Test (510K Number: K003845)

INSTANT-VIEW® Cocaine Urine Test (510K Number: K994403)

All by Alfa Scientific Designs, Inc.

Device Description	A one-step lateral flow chromatographic immunoassay. The device consists of any combination between one (1) to twelve (12) individual test strip(s) for the drug(s) being tested. Each test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a burgundy-colored band during test regardless of the presence of the drug.
Intended Use	The proposed test is a lateral flow, one-step immunoassay for the qualitative detection of one or more drugs or drug metabolites in urine specimens. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. The proposed test is for home use.
Similarity to the Predicate Devices	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Performance Characteristics	The proposed multi-drug of abuse device uses exactly the same technology and formulations for the detection of the drugs as individual test devices. The performance characteristics, such as accuracy, reproducibility, sensitivity and specificity of the multi-drug of abuse test are exactly the same as the individual tests, which have been 510(K) cleared previously or are filed in separated sections of this submission.
Stability	The shelf life stability of the test devices was estimated based on the accelerated degradation studies of individual test devices, three lots for each test, each format. Two years (24 months) shelf life of the proposed tests was predicted.
Formats of the Device	The proposed multi-drug of abuse device has two formats, cassette and urine cup. Both formats contain between one to twelve test strips, each for a drug.
Conclusion	The proposed test is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Alfa Scientific Designs, Inc.
c/o Dr. Daiting Rong
13200 Gregg Street
Poway, CA 92064

MAY - 7 2007

Re: k063545
Trade/Device Name: Instant-View® Amphetamine, Cocaine, Methamphetamine, Oxycodone, and Multi-Drug Urine Tests and Instant-Verdict® Amphetamine Cocaine, Methamphetamine, Oxycodone, and Multi-Drug Urine Tests
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DKZ, DIO, DJC, DIS, NFV, JXM, NCI, DJG, DJR, LCM, LFG, LDJ
Dated: March 07, 2007
Received: March 08, 2007

Dear Dr. Rong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~NA~~ K063545

Device Name:

INSTANT-VIEW® Amphetamine (300) Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® Amphetamine (300) Urine Test (Cassette, Dip-Strip)
Amphetamine (300) Urine Test (Cassette, Dip-Strip)

Indications For Use:

The Amphetamine (300) test is a qualitative immunoassay for the rapid detection of amphetamine from human urine specimens at a cutoff concentration of 300 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ (Pert 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063545

Indications for Use

510(k) Number (if known): ~~N/A~~ K063545

Device Name:

INSTANT-VIEW® Cocaine (150) Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® Cocaine (150) Urine Test (Cassette, Dip-Strip)
Cocaine (150) Urine Test (Cassette, Dip-Strip)

Indications For Use:

The Cocaine (150) test device is a rapid qualitative immunoassay for the rapid detection of cocaine (benzoylecgonine) from human urine specimens at a cutoff concentration of 150 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): N/A K063545

Device Name:

INSTANT-VIEW® Methamphetamine (300) Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® Methamphetamine (300) Urine Test (Cassette, Dip-Strip)
Methamphetamine (300) Urine Test (Cassette, Dip-Strip)

Indications For Use:

The Methamphetamine (300) test is a qualitative immunoassay for the rapid detection of methamphetamine from human urine specimens at a cutoff concentration of 300 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ (Pert 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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K063545

Indications for Use

510(k) Number (if known): ~~N/A~~ K063545

Device Name:

INSTANT-VIEW® Oxycodone (100) Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® Oxycodone (100) Urine Test (Cassette, Dip-Strip)
Oxycodone (100) Urine Test (Cassette, Dip-Strip)

Indications For Use:

The Oxycodone (100) test is a qualitative immunoassay for the rapid detection of oxycodone from human urine specimens at a cutoff concentration of 100 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): ~~N/A~~ K063545

Device Name:

INSTANT-VIEW® Oxycodone (300) Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® Oxycodone (300) Urine Test (Cassette, Dip-Strip)
Oxycodone (300) Urine Test (Cassette, Dip-Strip)

Indications For Use:

The Oxycodone (300) test is a qualitative immunoassay for the rapid detection of oxycodone from human urine specimens at a cutoff concentration of 300 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ (Pert 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): ~~N/A~~ K063545

Device Name:

INSTANT-VIEW® Multi-Drug of Abuse Urine Test (Panel, Cup)
INSTANT-VERDICT® Multi-Drug of Abuse Urine Test (Panel, Cup)
Multi-Drug of Abuse Urine Test (Panel, Cup)

Indications For Use:

The multi-drug of abuse device is a rapid qualitative immunoassay for screening potential abuse of one or more drugs listed below. The device detects any combination of the drugs or drug metabolites at or above the specified cut-off levels. It is for health care professional use.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
AMP300	Amphetamine	300 ng/ml
BAR	Barbiturates	200 ng/ml
BUP	Buprenorphine/Norbuprenorphine	10 ng/ml
BZD	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
COC150	Cocaine	150 ng/ml
MET	Methamphetamine	1000 ng/ml
MET500	Methamphetamine	500 ng/ml
MET300	Methamphetamine	300 ng/ml
MOR	Morphine	2000 ng/ml
MOR300	Morphine	300 ng/ml
MTD	Methadone	300 ng/ml
OXY100	Oxycodone	100 ng/ml
OXY300	Oxycodone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Tricyclics	1000 ng/ml
THC	Marijuana	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

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The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Indications for Use

510(k) Number (if known): ~~N/A~~ K063545

Device Name:

INSTANT-VIEW® Multi-Drug of Abuse Urine Test (Panel, Cup)
INSTANT-VERDICT® Multi-Drug of Abuse Urine Test (Panel, Cup)
Multi-Drug of Abuse Urine Test (Panel, Cup)

Indications For Use:

The multi-drug of abuse device is a rapid qualitative immunoassay for screening potential abuse of one or more drugs listed below. The device detects any combination of the drugs or drug metabolites at or above the specified cut-off levels.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
BAR	Barbiturates	200 ng/ml
BZD	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
MET	Methamphetamine	1000 ng/ml
MOR	Morphine	2000 ng/ml
MTD	Methadone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
TCA	Tricyclics	1000 ng/ml
THC	Marijuana	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Pert 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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